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Proposed Maximum Residue Limit

PMRL2010-06

Prothioconazole

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Under the authority of the *Pest Control Products Act*, Health Canada's Pest Management Regulatory Agency (PMRA) has concluded that the addition of a new use on flax (linseed) to the product label of Proline 480 SC Foliar Fungicide, containing technical grade prothioconazole, is acceptable. The specific use approved in Canada is detailed on the label of Proline 480 SC Foliar Fungicide, *Pest Control Products Act* Registration Number 28359.

The evaluation of this prothioconazole application indicated that the end-use product has merit and value and that the human health and environmental risks associated with the new use are acceptable. Details regarding the registration can be found in the corresponding Evaluation Report that is available in the Pesticides and Pest Management section of Health Canada's website, under Public Registry, Pesticide Product Information Database.¹

Before registering a pesticide for food use in Canada, the PMRA must determine the quantity of residues that are likely to remain in or on the food when the pesticide is used according to label directions and that such residues will not be a concern to human health. This quantity is then legally established as a maximum residue limit (MRL). An MRL applies to the identified raw agricultural food commodity as well as to any processed food product that contains it, except where separate MRLs are specified for the raw agricultural commodity and a processed product made from it.

Consultation on the proposed MRLs for prothioconazole is being conducted via this document (see Next Steps).

To comply with Canada's international trade obligations, consultation on the proposed MRLs is also being conducted internationally by notifying the World Trade Organization, as coordinated by the Standards Council of Canada.

¹ The relevant report can be accessed by selecting the Programs and Special Actions/Minor Use/Historical tab and opening the Evaluation Report found under Application Number 2008-4622. Note that the report includes crambe seeds, lesquerella seeds, lunaria seeds and meadowfoam seeds as commodities for which MRLs would be recommended, but that is not the case given the lack of food uses for these oilseeds.

The proposed MRLs for prothioconazole in Canada in or on food, to be added to the MRLs already legally established, are as follows.

Table 1 Proposed Maximum Residue Limits for Prothioconazole

Common Name	Residue Definition	MRL (ppm)	Food Commodity
Prothioconazole	2-[2-chloro-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-1,2-dihydro-3 <i>H</i> -1,2,4-triazole-3-thione, including the metabolite α -(1-chlorocyclopropyl)- α -[(2-chlorophenyl)methyl]-1 <i>H</i> -1,2,4-triazole-1-ethanol	0.15	Rapeseeds (Crop Subgroup 20-07A*)

* MRLs at 0.15 ppm are currently established for the subgroup commodities canola (rapeseed) and mustard seeds. This action proposes to extend the MRL to the remaining food commodities within the rapeseeds subgroup in accordance with Appendix I. In addition, the established MRL for "mustard seeds" is proposed for revision to "mustard seeds (oilseed variety)" to clarify that the MRL applies to oilseed mustard rather than condiment mustard varieties.

MRLs are proposed for each commodity included in the rapeseeds crop subgroup in accordance with Appendix I.

The residue definition for prothioconazole currently reflects the parent chemical only for both plant and livestock commodities. However, upon further review of supporting metabolism studies it was determined that the addition of metabolites to the residue definitions for both plant and livestock commodities was required. The residue definition for all plant commodities is proposed for revision to prothioconazole and the metabolite prothioconazole-desthio in accordance with Table 1 above. The residue definition for all livestock commodities is proposed for revision to prothioconazole, the metabolite prothioconazole-desthio and their conjugates.

A complete list of all MRLs established in Canada can be found on the Maximum Residue Limits for Pesticides webpage in the Pesticides and Pest Management section of Health Canada's website.

International Situation and Trade Implications

The proposed Canadian MRL for the rapeseeds subgroup is the same as the American tolerance established for "rapeseed, seed"; however, tolerances have not been established in the United States for any other oilseed commodities (tolerances are listed in the Electronic Code of Federal Regulations by pesticide). Currently, Codex² MRLs have not been established for prothioconazole on any commodity. A listing of all established Codex MRLs is available on the Pesticide Residues in Food website.

² Codex is an international organization under the auspices of the United Nations that develops international food standards, including MRLs.

Next Steps

The PMRA invites the public to submit written comments on the proposed MRLs for prothioconazole up to 75 days from the date of publication of this document. Please forward your comments to Publications. The PMRA will consider all comments received before making a final decision on the proposed MRLs for prothioconazole and posting a corresponding Established Maximum Residue Limit (EMRL) document in the Pesticides and Pest Management section of Health Canada's website.

Appendix I Crop Groups: Numbers and Definitions

Crop Group Number and Name		Crop Subgroup Number and Name		Food Commodities Included in the Crop Group or Subgroup
20-07	Oilseeds	20-07A	Rapeseeds	Borage seeds Cuphea seeds Echium seeds Flaxseed Gold of Pleasure seeds Hare's ear mustard seeds Milkweed seeds Mustard seeds (oilseed variety)* Oil radish seeds Poppy seeds Rapeseed (canola)* Sesame seeds Sweet rocket seeds

* MRLs at 0.15 ppm are currently established for these commodities

